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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/727,155	12/02/2003	John S. Babcook	ABGENIX.073A	5639

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Knobbe Martens Olson & Bear LLP
2040 Main Street
Fourteenth Floor
Irvine, CA 92614

EXAMINER

SKELDING, ZACHARY S

ART UNIT PAPER NUMBER

1644

DATE MAILED: 05/30/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/727,155	BABCOOK ET AL.	
	Examiner	Art Unit	
	Zachary Skelding	1644	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 20 March 2006.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 44, 45, 47-51 and 57-106 is/are pending in the application.
- 4a) Of the above claim(s) 44, 45 and 47-51 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 57, 59-65, 67, 68, 70-72, 74-82 and 84-106 is/are rejected.
- 7) ☒ Claim(s) 58, 66, 69, 73, 83 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

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1. Applicant's amendment filed March 20, 2006 has been entered.

Claims 1-43 and 46 have been canceled.

Claims 57-106 have been added.

Claims 44, 45, 47-51 and 57-106 are pending.

Newly added claims 57-106 are under consideration in the instant application as they read on fully human monoclonal antibodies to TNF- α .

Claims 44, 45 and 47-51 have been withdrawn as being drawn to a non-elected invention.

2. The rejections of record can be found in the previous Office Action, mailed December 19, 2005.

This Office Action is in response to Applicant's amendment filed March 20, 2006.

3. The previous objection has been withdrawn in view of applicant's amendment.

The previous rejection under 35 U.S.C. § 112, 2nd paragraph has been withdrawn in view of applicant's amendment to the claims.

The previous rejection under 35 U.S.C. § 112, 1st paragraph, enablement has been withdrawn in view of applicant's amendment to the claims.

The previous rejection under 35 U.S.C. § 112, 1st paragraph, written description has been withdrawn in view of applicant's amendment to the claims.

4. The application is required to be reviewed and all spelling, TRADEMARK, and like error corrected.

Trademarks should be capitalized or accompanied by the TM or ® symbol wherever they appear and be accompanied by the generic terminology. Although the use of trademarks is permissible in patent application, the proprietary nature of the trademarks should be respected and every effort made to prevent their use in any manner which might adversely affect their validity as trademarks.

Appropriate correction is required.

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5. Claims 59, 60, 62, 63, 67, 68, 75, 77, 78, 84, 85, 87, 88, 93, 96, 95, 99 and 103, and dependent claims thereof, are rejected under **35 U.S.C. 112, second paragraph**, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

A. Claims 60, 68, 75, 85, 99 and 103, and dependent claims thereof, are indefinite in the recitation of “299v2, 299v1, 263 and 269” because their characteristics are not known. The use of “299v2, 299v1, 263 and 269” as the sole means of identifying the claimed anti-TNF α antibodies renders the claim indefinite because “299v2, 299v1, 263 and 269” are merely laboratory designations which do not clearly define the claimed products, since different laboratories may use the same designations to define completely distinct biological materials.

Amending the claim to recite the appropriate Deposit Accession Number or SEQ ID NOs would obviate this rejection. See the rejection under 35 U.S.C. § 112, 1st paragraph for the deposit of biological materials below.

B. Claims 59, 67, 74, 84 and 93, and dependent claims thereof, are indefinite in the recitation of, “wherein said antibody, or **binding fragment thereof**, is a **complete** antibody,” because a binding fragment of an antibody is not a complete antibody.

C. Claims 62, 77, 87 and 95 are indefinite in the recitation of, “wherein the **antibody**, or binding fragment thereof, is a **binding fragment of an antibody**,” because an antibody cannot be a binding fragment of an antibody.

D. Claims 63, 78, 88 and 96, and dependent claims thereof, are indefinite in the recitation of, “wherein said antibody is **conjugated** to a therapeutic agent.” There is insufficient antecedent basis for this limitation in this claim. The base claims from which the rejected claims depend recite “fully human monoclonal antibody”, which is an **antibody**, not an **antibody conjugate**.

Applicant is suggested to amend the rejected claims to an independent claim which recites “an antibody conjugate” in the preamble, and then recite the elements of the conjugate.

E. Claims 61, 69, 76, 86, 94, 102 and 106 are indefinite in the recitation of, “wherein the antibody is **in association with** a pharmaceutically acceptable carrier.” There is insufficient antecedent basis for this limitation in this claim. The base claims from which the rejected claims depend recite “a fully human monoclonal antibody”, which is a **compound**, not a **composition** of an antibody and a pharmaceutically acceptable carrier.

Applicant is suggested to amend the rejected claims to an independent claim which recites that “a composition” is being claimed in the preamble, and then recite the elements of the composition.

Applicant is reminded that any amendment must point to a basis in the specification so as not to add new matter. See MPEP 714.02 and 2163.06.

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6. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

7. Claims 57, 60-65, 68, 70-72, 75-82, 85-98 and 99-106, are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

A. Claims 60, 68, 75, 85 and 99-106 are rejected under 35 U.S.C. 112, first paragraph because it is apparent that to practice the claimed invention anti-TNF α antibodies 299v2, 299v1, 263 and 269 are required. As required elements, anti-TNF α antibodies 299v2, 299v1, 263 and 269 must be known and readily available to the public or obtainable by a repeatable method set forth in the specification. If they are not so obtainable or available, the enablement requirements of 35 USC 112, first paragraph, may be satisfied by a deposit of the appropriate cell lines/hybridomas which produce the antibodies. See 37 CFR 1.1801-1.1809.

In addition to the conditions under the Budapest Treaty, applicant is required to satisfy that all restrictions imposed by the depositor on the availability to the public of the deposited material will be irrevocably removed upon the granting of a patent in US patent applications.

Amendment of the specification to recite the date of the deposit and the complete name and address of the depository is required. As an additional means for completing the record, applicant may submit a copy of the contract with the depository for deposit and maintenance of each deposit.

If the original deposit is made after the effective filing date of an application for patent, applicant should promptly submit a verified statement from a person in a position to corroborate the fact, and should state, that the biological material which is deposited is a biological material specifically identified in the application as filed, except if the person is an attorney or agent registered to practice before the Office, in which case the statement need not be verified. See MPEP 1.804(b).

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B. Furthermore, claims 57, 61-65, 70-72, 76-82 and 86-98 are rejected under 35 U.S.C. 112, first paragraph, because one of skill in the art would not know how to make a “fully human monoclonal antibody, or binding fragment thereof, that binds to Tumor Necrosis Factor- α , wherein the antibody or binding fragment thereof, *comprises*,” a particular light chain or heavy chain, for example, “a light chain polypeptide having the amino acid sequence of SEQ ID NO: 72” (claim 57), without further specifying a complementary light chain or heavy chain.

The scope of the claims must bear a reasonable correlation with the scope of enablement. See In re Fisher, 166 USPQ 18 24 (CCPA 1970).

In order to make a “fully human monoclonal antibody, or binding fragment thereof, that binds to Tumor Necrosis Factor- α ” one of skill in the art would need to know the sequences of both the heavy and light polypeptide chains because, as is well known in the art, formation of an intact antigen-binding site generally requires the association of the complete heavy and light chain variable regions of a given antibody, each of which consists of three complementarity determining regions (CDRs) which provide the majority of the contact residues for the binding of the antibody to its target epitope. The amino acid sequences and conformations of each of the heavy and light chain CDRs are critical in maintaining the antigen binding specificity and affinity which is characteristic of the parent immunoglobulin.

For example, Janeway et al. teach that all of the heavy and light chain CDRs in their proper order and in the context of framework sequences which maintain their required conformation, are required in order to produce a protein having antigen-binding function and that proper association of heavy and light chain variable regions is required in order to form functional antigen binding sites (See Janeway et al., Immunobiology, 6th Ed., Garland Science, pp. 110-112 (2004), cited in the previous Office Action).

The instant specification does not provide sufficient guidance or direction to enable one of skill in the art to screen for and isolate a, “fully human monoclonal antibody, or binding fragment thereof, that binds to Tumor Necrosis Factor- α ” given only a particular light chain or heavy chain, and undue experimentation would be required to practice the claimed methods with a reasonable expectation of success.

Thus, in view of the lack of predictability of the art to which the invention pertains, the lack of working examples, and the level of skill and knowledge in the art, undue experimentation would be required for one of skill in the art to make and use the “fully human monoclonal antibody, or binding fragment thereof, that binds to Tumor Necrosis Factor- α ” of the rejected claims.

Applicant’s argument of record set forth in the amendment filed March 20, 2006 has been fully considered but have not been found convincing. Applicant argues that by canceling the previously rejected claims the rejections of record are moot, and draws the Examiners attention to newly added claims 57-106.

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Applicant's argument is not found persuasive essentially for the reasons set forth in the previous office action and above.

8. Claim 59, 60, 67, 68, 74, 75, 84, 85 and 93 are rejected **under 35 U.S.C. 112, first paragraph**, as failing to comply with the **written description requirement**. The claims contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventors, at the time the application was filed, had possession of the claimed invention. The specification as originally filed does not provide support for "**complete antibody**". This is a *new matter* rejection.

Applicant's amendment, filed March 20, 2006, does not provide sufficient direction for the written description for the above-mentioned "limitation". The Examiner is unable to locate the written support for "**complete antibody**".

The specification as filed does not provide a sufficient written description of "**complete antibody**". The specification does not provide blazemarks nor direction for claims to "**complete antibody**". This limitation, which was not clearly disclosed in the specification as-filed, changes the scope of the instant disclosure as-filed. Such limitations recited in the present claims, which did not appear in the specification, as filed, introduce new concepts and violate the description requirement of the first paragraph of 35 U.S.C. 112.

Applicant is required to cancel the new matter in the response to this Office Action. Alternatively, applicant is invited to point out where the instant specification provides sufficient written support for "**complete antibody**". See MPEP 714.02 and 2163.06.

9. No claim is allowed.

However, claims 58, 66, 69, 73 and 83 are objected to as being dependent upon rejected base claims, and would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

10. Applicant's amendment necessitated the new grounds of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.


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11. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Zachary Skelding whose telephone number is 571-272-9033. The examiner can normally be reached on Monday - Friday 8:00 a.m. - 5:00 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached on 571-272-0841. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Zachary Skelding, Ph.D.
Patent Examiner
May 12, 2006


PHILLIP GAMBEL, PH.D., J.D.
PRIMARY EXAMINER
R-1600
5/12/06